Pfirramann relates to salts of dihydroorotic acid with primary, secondary or tertiary aliphatic amines. Suitable amines include aminoethanol and mono- and di- alkaylaminoethanols including methylaminoethanol, ethylaminoethanolok directhylaminoethanol, diethylaminoiethanol and methylethylaminoethanol. The dihydroorotic salts are taught to promote an easier flow of blood through the vascular system, produce improvements in depth of sleep, in the level of depression and exhaustion and general condition and alertness. See page 1, lines 45-53. The salts are also taught to influence symptoms of age appearing of the surface area of the body by eliminating the form of pigments. See page 2, lines 93-102.

In contrast to the teachings of Pfirramann, the present invention relates to methods (1) to improve skin firmness (claim 1); (2) to improve the appearance of facial contouts (claim 13); and (3) for reducing the appearance of sagging skin (claim 23).

Pfirramann fails to teach or suggest that the dihydroorotic acid salts could be used to improve skin firmness, improve the appearance of facial contours or reduce the appearance of sagging skin. Accordingly, since Pfirramann fails to teach all the elements of the claimed invention, Pfirramann cannot anticipate the present claims.

## III. Claim Rejections 35 U.S.C. § 103

#### A. The Rejection Over Yu et al.

The Examiner has rejected claims 1-6, 9-11, 13-17, 20, 22 and 23 as allegedly unpatentable over U.S. Patent No. 4,197,316 ("Yu et al."). Applicants respectfully traverse this rejection.

Yu et al. relates to compositions and methods for treating dry skin. The compositions comprise an acid, amide or ammonium salt of  $\alpha$ - or  $\beta$ - hydroxyacids or  $\alpha$ -ketoacids and esters thereof.

In contrast to the compositions and methods of Yu et al., the present invention relates to methods (1) to improve skin firmness (claim 1); (2) to improve the appearance of facial contours (claim 13); and (3) for reducing the appearance of sagging skin (claim 23).

Yu et al. fails to teach or suggest that the Yu et al. compositions could be used to improve skin firmness, improve the appearance of facial contours or reduce the appearance of sagging skin.

Application Serial No. 09/742,622 Attorney Docket No. JBP-534 Page 3 of 6

The methods taught by Yu et al. are clearly limited to the treatment of dry skin. There is nothing in the teachings of Yu et al. that would provide one of ordinary skill in the art with the motivation to use the  $\alpha$ - or  $\beta$ - hydroxyacids or  $\alpha$ -ketoacids in a method to improve skin firmness, improve the appearance of facial contours or for reducing the appearance of sagging skin. Clearly, there would be no expectation of success as the methods taught by Yu et al. are limited to the treatment of dry skin. Accordingly, Yu et al. fails to render the present claims obvious.

# B. The Rejection Over Yu et al. in view of Znaiden

The Examiner has rejected claims 7, 8, 18 and 19 as allegedly unpatentable over Yu et al. as applied to claims 1-6, 9, 11, 13-17, 20, 22 and 23 above and further in view of U.S. Patent No. 5,523,090 ("Znaiden et al.").

The Examiner recognizes that Yu et al. fails to teach the specific weight ratio of malic and glycolic acid and relies upon Znaiden et al. to cure the deficiencies of Yu et al. Applicants respectfully traverse this rejection.

As discussed above, Yu et al. fails to teach or suggest that the Yu et al. compositions could be used to improve skin firmness, improve the appearance of facial contours or reduce the appearance of sagging skin. Nothing in the teachings of Znaiden et al. cure these deficiencies of Yu et al.

Znaiden et al. relates to compositions and methods for treating cellulite. The compositions contain an alpha hydroxy acid and/or an inositol phosphoric acid in combination with a xanthine. The active ingredient taught by Znaiden et al. is clearly the xanthine and the inositol phosphoric acid. Indeed, Znaiden et al. specifically teach that the alpha hydroxy acid is added to improve skin penetration of the xanthine. See, for example, col. 5, lines 30-48. Further, there is nothing in the teachings of Znaiden et al. that would teach or suggest that the specific compounds recited in the present claims could be used in methods to improve skin firmness, improve the appearance of facial contours, or reduce the appearance of sagging skin. Applicants also note that Yu et al. relates to methods for treating dry skin while Znaiden relates to methods for treating cellulite. Clearly, one of ordinary skill in the art would not look to a method for treating cellulite in order to modify a method

Application Serial No. 09/742,622 Attorney Docket No. JBP-534 Page 4 of 6

for treating dry skin. For all these reasons, Applicants respectfully submit that Znaiden et al. fails to remedy the deficiencies of Yu et al. and the rejection should be withdrawn.

## C. The Rejection Over Yu et al. in view of Znaiden et al. and Perricone

The Examiner has rejected claims 10 and 21 as allegedly unpatentable over Yu et al. in view of Znaiden et al. and U.S. Patent No. 5,554,647 ("Perricone"). The Examiner recognizes that Yu et al. fails to teach the use of dimethylaminoethanol and relies upon Perricone to cure this deficiency. Applicants respectfully traverse this rejection.

As discussed above, each of Yu et al. and Znaiden et al. fail to teach or suggest that the compounds recited in the present claims could be used to improve skin firmness, improve the appearance of facial contours or reduce the appearance of sagging skin.

Perricone discloses a method for percutaneously treating aging skin using an acetylcholine precursor, e.g., ethanolamine ingredients in a dermatologically acceptable catrier. The ethanolamine is selected from the group consisting of dimethylaminoethanol, monoaminoethanol, choline, serine, acetic acid esters of dimethylaminoethanol, acetic acid esters of monoaminoethanol, parachlorophenylacetic acid esters of dimethylaminoethanol, para-chlorophenylacetic acid esters of monoaminoethanol, and mixtures thereof. These compounds are hypothesized to treat aging skin via a mechanism of neuromuscular stimulation, i.e., percutaneous delivery of the active ingredient in amounts effective to produce increased muscle tone.

Yu et al. relates to compositions and methods for treating dry skin. The compositions comprise an acid, amide or ammonium salt of  $\alpha$ - or  $\beta$ - hydroxyacids or  $\alpha$ -ketoacids and esters thereof. There is nothing in the teachings of Perricone that would provide one of ordinary skill in the art with the motivation to use the acetylcholine precursors as the amide to form the salt of the  $\alpha$ - or  $\beta$ - hydroxyacids or  $\alpha$ -ketoacids taught by Yu et al. Clearly, none of the references relied upon by the Examiner, taken alone or in any combination, teach or suggest Applicants claimed methods (1) to improve skin firmness; (2) to improve the appearance of facial contours; and (3) for reducing the appearance of sagging skin comprising topically applying to affected skin areas a composition comprising an effective amount of an acid salt formed from a compound selected from the group consisting of dimethylaminoethanol, trimethylaminoethanol, isoproanoldimethyl amine,

Application Serial No. 09/742,622 Attorney Docket No. JBP-534 Page 5 of 6

ethylethanolamine, 2-butanolamine and serine with a mixture of anionic counterions derived from at least two pharmaceutically acceptable acids and esters thereof and a cosmetically acceptable carrier.

# D. The Rejection Over Yu et al. In View of Quan et al.

The Examiner has rejected claim 12 as allegedly unpatentable over Yu et al. as applied to claims 1-6, 9, 11, 13-17, 20, 22, and 23 and further in vie w of U.S. Patent No. 6,180,133 ("Quan et al."). The Examiner recognizes that Yu et al. fails to teach or suggest the material carriers recited by claim 12 and relies upon Quan et al. to cure this deficiency. Applicants respectfully traverse this rejection.

As discussed above, Yu et al. fails to teach or suggest that the compounds recited in the present claims could be used to improve skin firmness, improve the appearance of facial contours or reduce the appearance of sagging skin. Quan et al. fails to remedy this deficiency of Yu et al.

Quan et al. relates to an anti-wrinkle skin treating composition comprising a pressure sensitive matrix patch having dissolved in the adhesive a mixture of antioxidants in the form of a Vitamin C ester and Vitamin E. In contrast to the claimed methods, Quan et al. relates to methods for treating wrinkles. Accordingly, none of the references relied upon by the Examiner, taken in any combination, teach or suggest the claimed invention. Applicants, therefore, respectfully request withdrawal of this rejection.

# IV. Double Patenting Rejection

The Examiner has provisionally rejected claims 1-11 and 13-23 as allegedly being unpatentable over claims 1, 2, 4-7, 10-12 and 14-16 of copending Application No. 09/677,737. Applicants respectfully traverse this rejection.

Copending Application No. 09/677,737, relates to methods for ameliorating redness or inflammation of mammalian skin and methods for ameliorating the irritating effects of a skin irritating composition. The copending application fails to teach or suggest the methods of the presently claimed invention for improving skin firmness, improving the appearance of facial contours or reducing the appearance of sagging skin. Accordingly, Applicants respectfully request withdrawal of this rejection.

Application Serial No. 09/742,622 Attorney Docket No. JBP-534 Page 6 of 6

#### V. Conclusion

Applicants believe that the foregoing presents a full and complete response to the outstanding Office Action. An early and favorable response to this Amendment is earnestly solicited. If the Examiner feels that a discussion with Applicants' tepresentative would be helpful in resolving the outstanding issues, the Examiner is invited to contact Applicants' representative at the number provided below.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 10-0750/JBP-534/EMH. If a fee is required for an Extension of time 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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